

REMARKS

Reconsideration of this application is respectfully requested. The indication of allowability of claims 11 and 13 to 15 is appreciated. Claim 11 has been rewritten into independent form and should be in clear condition for allowance. Claims 13 to 15 depend on claim 11 and should also be in clear condition for allowance.

Claims 11 to 15 have been amended in the manner suggested in the Action to overcome the rejection for indefiniteness. However, the grounds for the indefiniteness rejection of claim 11 for the lack of reciting "further comprising" was obviated by rewriting that claim into independent form.

The rejections of claims 1 to 7, 12 and 16 as being anticipated by Cywinski (US Patent 5,350,415) and by Campos (5,097,833) are traversed.

Independent claim 1 recites a signal applied to stimulate a muscle where:

"the signal comprises a series of regularly spaced bursts of pulses with each burst including a first component as a first continuous train of regularly spaced pulses and a second component as a series of regularly spaced second trains of regularly spaced pulses, the second component being combined with the first component and the spacing between successive pulses in the second pulse trains being less than the spacing between successive pulses in the first pulse train" (emphasis supplied).

A similar limitation is also recited in independent claim 16.

Cywinski and Campos do not disclose a signal that has regularly spaced "bursts", and do not teach signal bursts formed of a continuous low-frequency pulse train and a plurality of high frequency pulse trains.

Figure 2 to 4 of this application illustrate a series of signal "bursts" that are separated at, for example, at one minute intervals. Within each burst, there is a continuous low frequency pulse train and a series of high frequency pulse trains, as is shown in Figures 3 and 4. See also Figure 1 (which shows a single signal burst, but not a period between bursts) . Figure 2 shows the spaced apart bursts, and Figure 3 shows that each of the spaced apart bursts is made up of ten identical sections, one of those identical sections being illustrated in detail in Figure 4. In each of the spaced apart bursts, there is a first component which is continuous and a second component formed by a series of regularly spaced second trains of pulses. Each of the spaced apart bursts described in the embodiment disclosed in this application include one burst of pulses making up the first component and ten bursts of pulses making up the second component.

also includes
The dictionary definition of the term burst includes: "to appear or disappear suddenly"; "to make an abrupt beginning"; "a sudden intense outbreak"; "a brief, intense, or violent effort". Webster's Third New International Dictionary p. 301 (1993).

Accordingly, the regularly spaced bursts recited in claim 1 are periodic abrupt or sudden muscle stimulation signals, wherein each burst has a low frequency pulse train and a series of high frequency pulse trains.

CYWINSKI

Cywinski discloses a continuous pulse train that is applied for muscle stimulation.

The continuous pulse train disclosed in Cywinski has a varying repetition rate which includes: a low frequency component (impulse intervals (IPI) of 120 to 200 milliseconds); a second higher frequency component (IPI of 60-80 milliseconds), and a third still higher component (IPI of 10-20 milliseconds). Cywinski, col. 5, lns. 15 to 37.

*Clin doesn't say
it's
continuous*

The Cywinski pulse pattern is continuous and is not a series of bursts as recited in claim 1. That Cywinski periodically increases the repetition rate of the pulse train does not change the fact that the pulse train is continuous. Cywinski clearly envisages applying a continuous train of pulses to the patient for a predetermined period and thereafter stopping the treatment. There is no suggestion that Cywinski envisages applying a series of regularly spaced bursts of pulses.

In particular, Cywinski at column 5, line 15 refers to the "continuous low-rate firing activity", at column 5, line 21 refers to "continuously repetitive slow pulse activity", and at column 8, line 37 again refers to "a continuous low-rate firing activity". It is stated at Cywinski, column 8, lines 10 to 14, that the system stops the pulse generating means so as to stop the entire stimulator treatment until the next manual reset application after counting (in the described example) fifty clock pulses.

Cywinski refers at column 1 lines 37 to 40 and column 2 lines 3 to 5 to devices which are provided with "time on" and "time off" controls. These controls were proposed in the devices being discussed by Cwyinski to avoid painful muscle fatigue. The device

described by Cywinski does not envisage "time on" and "time off" controls because Cywinski had moved to a signal pattern at least in part modeled on natural non-stimulated signal patterns, that is to say voluntary contractions. Cywinski's understanding of the then knowledge is set out in columns 2 and 3. By going away from time on and time off controls, Cywinski teaches away from the present invention which generates bursts of pulses that each have multiple frequency components similar to natural muscle stimulation but applied only in the spaced apart bursts. *In re Geisler*, 43 U.S.P.Q.2d 1362 (Fed. Cir. 1997)(“a prima facie case of obviousness can be rebutted if the applicant . . . can show "that the art in any material respect taught away" from the claimed invention.”)

Further, Cywinski does not teach that during a signal burst there is a series of high frequency (second component) trains of pulses applied to a low frequency pulse train (first component), as is recited in claim 1. In contrast, the pulse pattern as envisaged by Cywinski is a continuous relatively low frequency train of pulses into which a series of relatively higher frequency components are interleaved at regular intervals, the higher frequency components starting with three or four pulses with a relatively low IPI followed by a slightly larger number of pulses with a relatively higher IPI. There is nothing to suggest that the Cywinski signals are spaced apart bursts with each of the bursts incorporating two components one of which is continuous through the bursts and the other of which is made up of a series of spaced apart bursts. Accordingly, Cywinski does not anticipate claim 1.

CAMPOS

The Action does not explain how Campos allegedly discloses the invention recited in the claims of this application. Accordingly, no case for anticipation or obviousness has been made out with respect to Campos.

Further, Campos describes a system that applies a continuous train of pulses to the patient. Nowhere in Campos is there any suggestion that pulses should be applied to the patient in the form of spaced apart bursts of pulses with the pulse structure within an individual burst being as specified in accordance with claim 1 of the present application. Accordingly, Campos does not anticipate or render obvious any claim of this application.

The rejection of claims 8 to 10 for obviousness over Cywinski is traversed for substantially the same reasons as stated above. Claims 8 and 10 depend on claim 1 and are distinguishable from Cywinski for the same reasons as stated above for claim 1. Further, the pulse train intervals and pulse timing recited in claims 8 to 10 have been rejected as obvious matters of design choice but without any evidence that such intervals and timing were considered in the prior art. Accordingly, the prior art does not teach the timings recited in claims 8 and 10 and these claims should not be rejected for obviousness.

DEPENDENT CLAIMS

Moreover, Cywinski and Campos do not disclose features recited in the dependent claims including: "a third component as a series of regularly spaced third trains of regularly spaced pulses" as is recited in claims 2 to 7; the same number of second and

OLDHAM

Serial No. 09/815,297

April 21, 2003

third pulse trains, as recited in claims 3, 4, 6 and 7; a third pulse train that precedes a second pulse train, as is recited in claim 4, or a third train having just two pulses as is recited in claims 5 to 7.

The rejection of claims 8 to 10 and 12 for obviousness over Campos (US Patent No. 5,097,833) is traversed. Claims 8 to 10 and 12 depend on claim 1, which is not rejected in view of Campos. The burst signals recited in claim 1 are not disclosed or suggested in Campos. Moreover, Campos does not teach the pulse train intervals and pulse timing recited in claims 8 to 10.

Further, the statement that his application names joint inventors (see Action, page 4) is incorrect as this application names a sole inventor.

To overcome the obviousness double patenting rejection a terminal disclaimer is being prepared and will shortly be submitted to the USPTO.

All claims are in good condition for allowance. If any small matter remains outstanding the Examiner is requested to telephone the undersigned. Prompt reconsideration and allowance of this application is requested.

OLDHAM

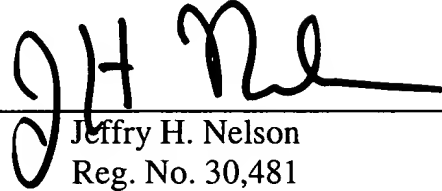
Serial No. **09/815,297**

April 21, 2003

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

A handwritten signature in black ink, appearing to read "JH Nelson", written over a horizontal line.

Jeffrey H. Nelson

Reg. No. 30,481

JHN:glf

1100 North Glebe Road, 8th Floor

Arlington, VA 22201-4714

Telephone: (703) 816-4000

Facsimile: (703) 816-4100